INTRAVENOUS CARDIAC LEAD WITH POSITIVE FIXATION SEGMENT

BACKGROUND OF THE INVENTION

I. **Field of the Invention:** This invention relates generally to a cardiac pacing lead designed for placement in a coronary vein, and more particularly to such a lead employing a preformed shape in a distal end portion thereof for holding the distal end portion of the pacing lead carrying the stimulating electrode in place and for increased lead flexibility.

II. **Discussion of the Prior Art**: Cardiac pacemakers for treating bradycardia commonly employ pacing leads for connecting an electrical pulse generator to excitable cardiac tissue, usually within the heart's right ventricle. Such leads have one or more electrodes proximate the distal end thereof and also commonly employ tines located just distal of the tip electrode for holding that electrode in contact with endocardial tissue in the right ventricle. The tines engage the trabeculae, resisting movement of the lead tip due to body movement and/or contractions of the heart muscle itself.

More recently, researchers have found that cardiac stimulation can have a beneficial effect in treating patients suffering from congestive heart failure (CHF). By properly controlling the AV interval of the pacemaker, a sick heart may be made to pump more efficiently. Pacing therapy for the treatment of CHF, however, often requires the ability to stimulate the left ventricle, either alone or in conjunction with right ventricular stimulation. Current methods for achieving left ventricular pacing require placement of an epicardial lead, via thoracotomy or a thoracoscopic approach. Because of the usual poor condition of CHF patients, both of these procedures are "high risk" due to the trauma of the surgery itself and the need for general anesthesia. To obviate the need for a thoracotomy, left ventricular access (LVA) leads have been developed that may be introduced through the coronary sinus

and then advanced through the coronary veins so that the lead's stimulating electrode can be positioned on the surface of the left ventricle near the apex of the heart.

Those skilled in the art knowing the anatomical configuration and dimensions of the coronary veins on the heart can appreciate that a lead to be routed therethrough must be of a relatively small diameter as compared to a conventional pacing lead adapted for placement in the right ventricle. Heart motion and respiratory motion as well as blood blow or other body movement are typical mechanisms for lead dislodgment. As such, a means must be provided for at least temporarily anchoring the electrode at a desired selected location until tissue ingrowth and resulting lead stabilization occurs. Additionally, a means must be provided to decouple the relative motion of the heart from the distal tip of the lead thereby reducing trauma to the coronary vein and neighboring myocardium. These problems are deemed to be more acute in CHF patients due to the dilated condition of CHF hearts and general diseased state of the tissue.

It can be seen, then, that a need exists for a pacing lead that can readily be advanced through the coronary sinus and thence through a coronary vein on the heart and having an anchoring and stress-relieving structure for safely maintaining the electrode at a desired site notwithstanding heart motion, respiratory motion blood flow and other body movement.

SUMMARY OF THE INVENTION

The present invention comprises an implantable lead for placement in a selected coronary vein. It includes a lead body with at least one electrode carried thereon at a distal end portion thereof and an elongated conductor contained within the lead body electrically joining a terminal pin at a proximal end of the lead body to the electrode at its distal end. To temporarily anchor the distal end portion of the lead body within the selected coronary vein until such time that tissue ingrowth can be

3

relied upon for retention, the lead includes a distal end portion exhibiting a wave-like configuration with a plurality of longitudinally spaced peaks and valleys such that the lead body engages the vein wall at discrete points for inhibiting displacement of the electrode because of body movement, respiratory movement, beating action of the heart and flow of blood in the vein occupied by the lead. Additionally, the wave-like configuration adds resiliency to the lead body thereby reducing the dislodgment forces transmitted to the electrode and causing less injury to the vessel.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of a left coronary pacing lead, the distal end portion being shown within the lumen of a distal portion of coronary vein;

Figure 2 is a cross-sectional view of the lead of Figure 1 taken along the line 2-2 in Figure 1;

Figure 3 is a cross-sectional view taken along the line 3-3 in Figure 2;

Figure 4 is a greatly enlarged view of a segment of the distal end portion of the lead of Figure 1;

Figure 5 is a cross-sectional view taken along line 5-5 in Figure 1 showing an alternative lead construction; and

Figure 6 is a greatly enlarged view of a segment of the distal end portion of the lead of Figure 1 incorporating an external shaping member; and

Figure 7 is an enlarged longitudinal cross-sectional view of a portion of the lead body with an internal shaping member.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figure 1, there is indicated generally by numeral 10 a pacing lead specifically designed to be routed through the coronary sinus and into the great cardiac vein or branch vein, traversing the epicardium of the left ventricle. A segment of vein is identified by numeral 12. The lead preferably comprises an elongated flexible outer insulating polymer jacket 14 that surrounds an inner,

helically wound conductor 16. The conductor 16 extends the full length of the lead from its proximal terminal pin 18 to an electrode 20 affixed near the distal end of the lead body.

In accordance with the present invention, a portion of the lead body located just proximal of the distal electrode 20 is preformed to exhibit a wave-like appearance defining a plurality of peaks 22 and valleys 24 which lie substantially in one plane. With no limitation intended, the outer jacket 14 of the lead body may have a O.D. in the range of from about 3 Fr to 5 Fr (0.039-0.065 in.) and the wave-like portion may be located proximally from the lead tip and may span a zone about 4-7 centimeters in length. The peak-to-peak amplitude of the undulations in the lead body might typically be in a range of from 0.5-4.0 centimeters.

The amplitude and frequency of the wave shape is intended to cause the lead 10 to make intermittent contact with the wall of the vein 12. The force exerted on the vessel wall by the built-in bias property provides resistance to extraction forces attributable to heart motion, respiratory motion and blood flow in the vasculature. The resiliency imparted to the lead by the wave shape absorbs heart and respiratory motion forces, thereby decoupling the mechanisms of dislodgement from the distal end of the lead. Both attributes of the built-in bias act to stabilize the electrode in its initial implant position without injury or damage to the vessel or underlying myocardium.

The wave-like shape may be imparted to the lead by preforming the conductor coil 16 prior to the application of the polymer jacket 14 so that when the lead is unconstrained, the distal end portion will assume the wave-like configuration. Alternatively, the bias may be imparted to the lead in a zone near its distal end by selective molding of the insulating polymer jacket 14 over the coiled conductor 16.

With the conductor 16 being helically wound, it defines an internal lumen 26. The shape-biased lead is preferably implanted by tracking over a guidewire passed through the tubular terminal pin 18 and through the lumen 26 of the lead body. The guidewire overcomes the bias built into the lead and effectively straightens out the wave comprising the retention portion of the lead as it is being routed through the vascular system, the coronary sinus and into the great cardiac vein and branch vein. Alternatively, a stiff stylet may be used to straighten out the bias for routing through the coronary vascular system. Once the electrode 20 is positioned at a desired site, the guidewire or stiffening stylet is withdrawn, allowing the built-in bias to restore the wave-like shape to the anchoring portion of the lead so that it will engage the walls of the coronary vein at each peak and valley.

An enhancement of the above-described concept is illustrated in Figure 4. Here, a stiffening element 28 is added at discrete, spaced-apart locations within the wave-like shape imparted to the lead body. The stiffening elements 28 are disposed on the helical wound conductor and may be composed of, for example, thin-walled heat shrink PTFE tubing. These tubing segments 28 increase the contact force between the lead body and the blood vessel wall 12, causing the reinforced bends to function as anchoring points as previously described while other bends not reinforced with the shrink-tubing function to decouple movements of the lead body from displacing the electrode 20 from its desired stimulating site.

A further embodiment of the present invention is shown in Figure 5 and comprises a lead having a braided cable conductor with an adjacent lumen 32 extending along side it from the distal tip to the terminal pin and of sufficient size to accept a guidewire or stiffening stylet therein. Wave-like shapes can be imparted to such a lead by means of premolded portions of the lead body as previously explained with the aid of Figure 4 by including shaping elements

within the lead body, such as an external shaping coil as at 34 in Figure 6 or an internal shaping coil as at 36 in Figure 7 or even a premolded polymer shaping element as at 38 in Figure 5.

A distinct advantage of the present invention resides in the intermittent points of the contact between the lead body and the vessel wall. This offers an advantage over prior art coronary sinus leads, such as that described in the Ayers Patent 5,476,498. The Ayers lead has a helical bias that places the lead body in substantial contact with the wall of the great cardiac vein or coronary sinus over the length of the helix. Experiments have shown that a lead in contact with the vessel wall elicits a histological response that encapsulates and attaches the lead to the endothelial wall of the blood vessel in which it is placed. The helical fixation places a substantial surface in contact and greatly complicates any chance of using standard removal techniques should it become necessary to explant the lead. In dog experiments which have been conducted, it has been demonstrated that a "saw-tooth" wave bias tends only to elicit encapsulation at the intermittent points of contact with the vessel wall, thereby reducing the degree of involvement and, hence, facilitating lead removal following histological maturation.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is: